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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,485	08/01/2001	Sanchis Vincent	03495.0151-02000	4802

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EXAMINER

CARLSON, KAREN C

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/918,485	<b>Applicant(s)</b> VINCENT ET AL.	
	<b>Examiner</b> Karen Cochran Carlson, Ph.D.	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-18,21-27,29-31 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18,21-27,29-31 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/094,382.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/26/01</u> . | 6) <input type="checkbox"/> Other: _____  |

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his Office Action is in response to the paper filed August 20, 2004. Claims 1-14, 19, 20, 28, and 32-36 have been canceled. Claims 15-18, 21-27, 29-31, and 37-41 are currently pending and are under examination.

Priority is set to June 10, 1987.

#### **Withdrawal of Objections and Rejections**

The objection to the disclosure for the need to update the priority data is withdrawn.

The rejection of Claims 15-18, 29-31, 37-39, and 41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-14, 16, and 17 of U.S. Patent No. 6,110,734 is withdrawn due to the terminal disclaimer filed August 20, 2004.

#### **Maintenance of Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18, 21-27, 29-31, and 37-41 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 15, it is not clear what "the N-terminal region of a polypeptide is", that is, is it from the middle amino acid to the N-terminal, or the polypeptide lacking the C-terminal amino acid? Or? See also Claim 17, 21, and now Claims 29 and 41.

In Claim 29 and 41, the parameters of "hybridization" are not set forth. Because hybridization parameters can vary, the nucleic acids obtained from the claimed method are not limited in a meaningful way.

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Regarding the restriction fragments, without a description of the nucleic acid the fragments are indefinite in Claims 15-18, 21, 25-27, 29, and 41.

New due to amendments to the claims, Claim 21 refers to amino acid residues without providing a reference SEQ ID number. Therefore, the intended sequence is indefinite because no reference sequence is provided.

Applicants urge that the amendments to the claims should be sufficient to overcome this rejection. First, for example, the indefiniteness of the N-terminal region is not overcome because the "comprising" language is used and this region can still be any part of the encoded polypeptide short of the most C-terminal amino acid. This is not corrected by reference to the 3 kb HindIII-Pst-I DNA fragment from *B. thuringiensis* because the *B. thuringiensis* comprises numerous strains and Applicants are not referring to a deposited strain as they allude to on page 11, para. 3.

It appears that Applicants intended to overcome the rejection based on hybridization language but the parameters were not set forth in amended Claims 29 and 41.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-18, 21-27, 29-31, and 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Claims are drawn to nucleic acids encoding a polypeptide described as having toxic activity toward the larvae of Lepidoptera; however, no structure is provided for either the nucleic acid or the encoded polypeptide, whether claimed as nucleic acid encoding, or nucleic acid hybridizing to a nucleic acid, or genes encoding a 130kD protein, for example. See all of the claims where structure is not correlated with function. Therefore, the claims lack written description because the specification does not describe nucleic acids or encoded polypeptides that have no correlation of structure with function.

Applicants urge that the amendments to the claims now provide a correlation of structure with function. As noted in the response to the rejection under 35 USC 112, 2<sup>nd</sup>, the sequence references and nucleotide references are indefinite. Without a structure in hand such that one skilled in the art can readily obtain or understand the intended nucleotide sequence, the structure does not correlation with function.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371 (c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 15, 17, 29, 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Witt et al. (USP 5, 110,905; priority to June 14, 1985).

Witt et al. teach *B. thuringiensis* delta-endotoxin which is active against the larvae of Lepidoptera. Plasmid pK15 and pK8-1 comprise the gene encoding delta- endotoxin (See Example 2; instant Claims 15). These plasmids were transformed into *E. coli* (Claims 17, 18). Because the hybridization conditions are not set forth in Claims 29 and 41, it is presumed that this nucleic acid encoding *B. thuringiensis* delta-endotoxin will hybridize to nucleic acid encoding SEQ ID NO: 2 and therefore these claims are included in this rejection.

Applicants urge that Wit et al. do not teach *B. thuringiensis* var *aizawai* 7-29 and therefore does not apply to the claimed invention. Those claims referring to *aizawai* 7-29 have not been rejected.

No Claims are allowed. Applicants are again strongly encouraged to review the claim language of parent patents USP 5,792,928, 6,310,035, and 6,110,734 to advance the prosecution of this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER